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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,191	07/11/2003	Karl F. Popp	24948	3528
20529 7590 03/06/2007 NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT 1615	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.		Applicant(s)	
	10/617,191		POPP, KARL F.	
	Examiner		Art Unit	
	Lakshmi S. Channavajjala		1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of amendment and response dated 11-29-06 is acknowledged.

Claims 1-28 are pending.

Response to Arguments

Applicant's arguments filed 11-29-06 have been fully considered but they are not persuasive.

Examiner notes that the previous action failed to reject instant claim 12.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-12, 14-26, 30-34 and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,117,843 to Baroody et al (Baroody).

Instant claims are directed to a composition, a method of preparing the composition and a method of treatment, wherein the composition comprises a storage-stable mixture of benzoyl peroxide dispersion, clindamycin and a pharmaceutically acceptable carrier, before mixing and a final pH of 4.5 to 5.0.

Baroody discloses a composition comprising clindamycin, benzoyl peroxide and a carrier, for the treatment of acne, which is stable for several months (col. 2, L 3-66). Baroody discloses incorporating clindamycin salt that is compatible with the gelling agent and a dispersion of finely divided benzoyl peroxide, wherein the dispersion and

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clindamycin is combined with a carrier, and further with a gelling agent such as Carbopol (col. 4, L 1-43). Table 1 of Baroody shows final composition, which contains the claimed amounts of benzoyl peroxide and clindamycin, and has a pH of 4.5-5.5, which includes the pH of the instant claims. Thus, Baroody discloses the composition for the same purpose claimed in the instant application (claims 17-25, in particular claim 22 of the instant application). For claims 2 & 3, Baroody discloses applying the composition once or twice daily (col. 7, L 25-35). For claimed stability (claims 7-8), Baroody shows that the composition is stable over a long period of time (table 7 and 8). For claims 23-25, Baroody does not specify the age group of patients that are treated with the composition. However, the examples show that the composition is highly effective against acne (col. 15-16) and therefore the composition of Baroody is effective against all the age groups (including those claimed). With respect to the viscosity, Baroody discloses that initial viscosity of benzoyl peroxide in the range of 50,000 to 90,000 and a final viscosity in the range of 70,000 to 120,000.

While Baroody fails to disclose the claimed stability, the composition of Baroody has the same components recited in the instant claim and accordingly, the claimed stability is an inherent property of the composition of Baroody. Thus, anticipates instant claims.

Instant rejection includes claim 12, for the reasons mentioned above. In addition to the above reasons, claim 1 is presented as a product by process, where the process limitations do not carry patentable weight. "[E]ven though product-by-process claims are limited by and defined by the process,

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determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Instant claims, as presented do not distinguish from the composition of Baroody, in terms of the final viscosity. Accordingly, whatever the initial viscosity of the benzoyl dispersion is, the resulting product (claimed) is indistinguishable from the composition of Baroody.

New claims 36 and 37 are rejected for the reasons mentioned above. It is noted that the claims do not recite any specific viscosity.

RESPONSE: *Applicants argue that the final viscosity of the composition is lower than the viscosity of benzoyl peroxide dispersion, whereas in contrast, Baroody specifically state that the benzoyl peroxide component itself may be maintained at a relatively low viscosity while the final topical composition (which is at a different pH) will have a relatively higher viscosity. It is argued that according to Baroody, mixing of the two components to form the topical composition is facilitated (i.e. the lower viscosity of the benzoyl peroxide component makes the combination and mixing with the clindamycin component easier) while the final topical composition can still possess the desired higher viscosity, gel consistency. Applicants argue that not only does the Baroody et al. reference fail to disclose the requirement of the presently pending claims that the final composition has a viscosity lower than the viscosity of the intermediate benzoyl*

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peroxide dispersion, but the Baroody et al. reference teaches the exact opposite, requiring the final composition to have a viscosity higher than the benzoyl peroxide intermediate composition and hence does not anticipate the presently pending claims because it 1) fails to disclose each and every element of the presently pending claims as required by Verdegaaal Bros. v. Union. Oil Co. of California; and 2) actually teaches the exact opposite of, and thus teaches away from, the presently pending claims. Examiner further notes that instant claim 1 has been amended to include the process limitations and the stability of the composition.

Applicants' arguments have been considered but not found persuasive because instant claim 1 does not recite a specific final viscosity so as to distinguish the composition from that of Baroody. Accordingly, even though the claims have been amended to include the process of preparation, the resulting composition (from the claimed process steps) is indistinguishable from the composition of Baroody. With respect to the stability of the composition of claim 1 and new claim 36, while Baroody does not specifically teach the claimed stability, the composition of Baroody is no different from that of the instant claims (as written). Instant specification does not provide any evidence that the claimed compositions actually possess lower viscosity than the viscosity of benzoyl peroxide. With respect to the stability at less 6 degrees C, while Baroody measure the stability of the composition at 40 C and not at lower temperatures, Baroody states that their composition is adequately stable and has a long storage stability even without refrigeration (col. 2, L 12-16) and also stable for several months at room temperature (col. 3, L 8-12). Further, Baroody clearly states that

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clindamycin solution is stable and does not precipitate even when exposed to refrigeration (which is less than 6 degrees C, as claimed). With respect to the arguments regarding the final viscosity, in addition to the fact that instant claims do not recite any specific viscosity, the teachings of Baroody that the final viscosity is higher is not an absolute requirement for the composition. Instead, Baroody only states that the viscosity may be adjusted to higher viscosity. Hence the rejection has been maintained.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 13, 27-29 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,117,843 to Baroody et al (Baroody).

Baroody does not teach the purity of benzoyl peroxide, viscosity of benzoyl peroxide of claim 13, the percentage degradation of clindamycin or the amounts of benzoyl peroxide and clindamycin in the claimed standard deviation. However, Baroody also recognize the same factors i.e., pH, viscosity etc., that affect the stability (result-affective variables) of the composition and therefore it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ pure active compounds and optimize the general conditions such as viscosity, amounts of active agents with an expectation to achieve a composition that stable for long periods of time because the teachings of Baroody are also directed to preparing a storage stable composition comprising benzoyl peroxide and clindamycin and employed

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for the same purpose similar to the instant invention i.e., treatment of acne or other skin related conditions that need require benzoyl peroxide and clindamycin combination.

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

RESPONSE: *Applicants argue that the reference of record does not teach or suggest applicants' inventive subject matter as a whole as recited in the claims and that examiner has failed to establish a prima facie case of obviousness against the presently rejected claims. Applicants reiterate the above arguments made regarding the teaching of Baroody and state that Baroody does not teach, disclose, or render obvious any of the presently pending claims because it fails to disclose the requirement of the presently pending claims that the final composition has a viscosity lower than the viscosity of the intermediate benzoyl peroxide dispersion, but instead teaches the exact opposite, requiring the final composition to have a viscosity higher than the benzoyl peroxide intermediate composition. Accordingly, the Baroody et al. reference does not teach, disclose, or render obvious any of the presently pending claims.*

Applicants' arguments are not persuasive because as explained above, instant claim do not distinguish from the compositions of Baroody in terms of the components that make up the composition, percentages, pH, stability etc. With respect to the viscosity of initial benzoyl peroxide dispersion and final viscosity of the composition

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(claims 9-11 and claims 26-34), Baroody teaches a range of viscosities of benzoyl peroxide dispersion and the final viscosities, that overlap with the claimed viscosities and hence the argument is not persuasive. Further, Baroody recognizes that viscosity achieved by the addition of a gelling agent such as carbomer, is a function of pH (see col. 5, L 45-67, table 3). Baroody suggest adjusting the viscosity of the benzoyl peroxide by choosing the appropriate amounts of gelling agents and pH. While the reference teaches that one "may" choose to have a final viscosity higher than the initial viscosity, applicants have not show that the viscosities of the Baroody compositions are different from that of instant. Accordingly, in the absence of any unexpected results comparing the compositions of Baroody with that of the instant claimed composition as well as process, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to choose the appropriate amounts of gelling agents and pH so as to adjust the viscosity of the initial benzoyl peroxide dispersion and that of the final composition and still achieve the claimed stability. Therefore, the rejection has been maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



AU 1615
March 2, 2007

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER